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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/046,622

01/10/2002

Guoqing Chen

A-737A

2922

21069

7590

06/25/2004

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EXAMINER

KUMAR, SHAILENDRA

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/046,622

Applicant(s)

CHEN ET AL.

Examiner

SHAIENDRA - KUMAR

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,6-9 and 12-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,10,11 and 35-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/17/02, 10/21/02, 1/24/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This office action is in response to applicants' communication filed on 4/13/04.

Claims 1-43 are pending in this application.

Applicants' election of Group V (wherein A is 6 membered heteroaryl) is acknowledged.

Inasmuch as applicants have not traversed, the election is presumed to be without traverse and is made FINAL.

Applicants also elected species of Example 65, page 241, and acknowledges that claims 1, 4-5, 10-11 and 35-43 read on the elected species. It should be noted that these claims will be examined to the extent they read on the elected species and the subject matter closely related to the species. Thus claims 2-3, 6-9, and 12-34 are withdrawn from the consideration being drawn to the non elected subject matter.

The elected species was found to free of prior art and allowable. The examiner searched another species, wherein A is pyridine, X is the formula as claimed, R4 is direct bond, R1 is methyl substituted phenyl, R5a is hydrogen, R5 is hydrogen, and R is trifluoroalkyl substituted phenyl, and in view of the prior art found while searching the latter species, which clearly anticipate instant claimed compounds, the election requirement is given force and effect. MPEP Sec. 803.02.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 6/17/2002, 10/21/2002, and 1/29/04 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 36-37, 40-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 35 is drawn to the treatment of cancer, claim 40 is drawn to the method of treating KDR related diseases, and claim 40 is drawn to the method of treating proliferation related disorders.

Enablement is considered in view of the Wands factors(MPEP 2164.01(a)). These include: nature of the invention, guidance of the specification, the existence of the working examples, predictability of the prior art, state of the prior art, and the amount of the experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

**Nature of the invention:** Claim 35 is drawn to the treatment of cancer, claim 40 is drawn to the method of treating KDR related diseases, and claim 40 is drawn to the method of treating proliferation related disorders.

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**Breadth of the claims:** The complex nature of the claims greatly exacerbated by breadth of the claims. The claims encompass treating cancer, KDR related diseases, and proliferation related diseases.

**Guidance of the specification:** The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treat cancer, KDR related diseases, and proliferation related diseases. The guidance provided by the specification is simply directed to treatment of cancer, KDR related diseases and proliferation related disorders, and not to any specific cancer or other diseases.

**Working examples:** there are no working examples provided that suggest any treatment of any kind whatsoever.

**State of the art:** while the state of the art is relatively high with regard to the treatment of various types of cancer and KDR related diseases, and proliferation related diseases. The state of the art with regard to the such broad classes of millions of compounds for treating all the above diseases is underdeveloped. In particular, there is no known anti cancer agent that will be effective against all the cancers, at the same time will be effective against all the KDR related diseases and against proliferative diseases.

**Predictability of the art:** the lack of significant guidance from the specification or prior art with regard to the actual treatment of cancer, KDR related diseases, and proliferation related diseases in human subject with such broad class of compounds as claimed, makes practicing the claimed invention unpredictable.

**The quantity of experimentation necessary:** Applicants have failed to provide guidance and information as to allow the skilled artisan to ascertain which particular

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type of cancer and KDR related diseases and proliferation related disorders, the claimed compounds are effective against without undue experimentation. The limited disclosure of the few cancer and other diseases are noted, but will not support all the related diseases. Applicants need to test at least each class of these millions of compounds claimed for various cancers and KDR related and proliferation related diseases.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4-5, 10-11, and 35-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, fails to define R5a in the formula for X, thus rendering the claims indefinite.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4-5, 10-11 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by ES 462 495.

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ES'495, page 24, lines 3-4 anticipate instant compounds and composition. Also see, attached English Registry abstract.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR  
Primary Examiner  
Art Unit 1621

S.Kumar  
6/24/04